MAR 2 1 2013

Chapter 4. 510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 807.92.

1. Submitter Information

Sponsor Name: Sunray Medical Apparatus Co., Ltd.
Address: 4/F No. 242 Tianhe Dong Road, Guangzhou, PR China
Contact Person: Rong Jingbo (R&D Director)
Tel: +86-20-87570362 / 87502927
Fax: +86-20-87583004 / 87514127
Email: rongjb@sunray.cn

Application Correspondent Information:
MEDLAB (Shenzhen) Information Service Co., Ltd.
Address: Rm. 2706-Building A, Zhongfang Jingyuan, Futian District, Shenzhen, PR China, 518034
Contact Person: Ms. Sabrina Wei (Manager)
Tel: +86-755-83089699
Fax: +86-755-83089760
Email: sabrinawei@hotmail.com

2. Subject Device Information

Type of 510(k) submission:	Traditional
Common Name:	Fetal Monitor
Trade Name:	Fetal Monitor, model: SRF618B5
Classification Name:	Perinatal monitoring system and accessories
Review Panel:	Obstetrical and Gynecological
Product Code:	HGM, HGL
Regulation Number:	884.2740
Regulation Class:	2

3. Predicate Device Information

Sponsor:	Bionet Co., Ltd.	Bionet Co., Ltd.
Device Name:	FC-700	FC-1400
510(k) Number:	K043597	K043598
Product Code:	HGM	HGM
Regulation Number:	884.2740	884.2740
Regulation Class:	2	2

4. Device Description

SRF618B5 is a fetal monitor, providing continuous monitoring, displaying, printing and recording of single or twin (optional) Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) for antepartum testing and monitoring. SRF618B5 irradiates the ultrasound wave to maternal abdomen, and detects the Doppler effect signal reflected from the heart of the fetus. SRF618B5 extracts FHR and FM from this signal and provides the fetal heart beat sound with internal speaker.

SRF618B5 measures the UA of a pregnant woman using TOCO sensor.

SRF618B5 displays FHR, UA and FM with waveforms and numbers on the color LCD screen, saves them in internal flash memory and prints parts of them to review in details.

5. Intended Use

SRF618B5 Fetal Monitor detects and displays single or twin (optional) Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) in a real time on the color LCD viewer, and also provides the fetal heart beat sound with internal speaker. Ten hours of tracing may be stored and later retrieved for printing. It is intended for antepartum use by trained healthcare personnel. It is not intend for home use.

6. Test Summary

SRF618B5 Fetal Monitor has been evaluated the safety and performance by lab bench testing according to the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- IEC 60601-2-37, Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment, 2001+A1:2004+A2:2005
- IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety

and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2001+A1:2004

- ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing, 2003
- ISO 10993-5, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity, 2002+A1:2006

7. Comparison to Predicate Device

Compare with predicate devices, the subject device is very similar in design principle, intended use, indication for use, functions, material and the applicable standards. The following differences between subject device and predicate devices do not raise and new questions of safety or effectiveness.

(1) Although the Power Supply, Working and Storage Environment, Dimensions and Weight, and some Safety Degree of subject device are a little different from predicate devices, they are both compliance with IEC 60601-1 requirements.

(2) Although some specifications of FHR (Fetal Heart Rate) and UC (Uterine Contraction Pressure) measurement for subject device are a little different from predicate devices, they can conduct their function normally.

(3) Although some specifications of Printer & Recorder, Display & Sound for subject device are a little different from predicate devices, these are only assistant functions.

(4) Although some Ultrasound Transducer Specification of subject device is a little different from predicate devices, they are both compliance with Track 1 requirement of "Guidance for Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers".

Conclusions: The subject device has all features of the predicate devices. The differences do not affect the safety and effectiveness of the subject device.

8. Conclusion

The subject device has all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject device.

Thus, the subject device is substantially equivalent to the predicate devices.

9. Summary Prepared Date: 17 January 2013

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2013

Sunray Medical Apparatus Co., Ltd.
% Ms. Sabrina Wei
Project Manager
MEDLAB (Shenzhen) Information Service Co., Ltd.
B102, Nanshan Medical Devices Industrial Park
No.1019 of Nanhai Ave.
SHENZHEN GUANGDONG 518067
P.R. CHINA

Re: K123335
Trade/Device Name: Fetal Monitor, model: SRF618B5
Regulation Number: 21 CFR§ 884.2740
Regulation Name: Perinatal monitoring system and accessories
Regulatory Class: II
Product Code: HGM, HGL
Dated: January 17, 2013
Received: March 4, 2013

Dear Ms. Wei:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Chapter 3. Indications for Use

Indications for Use

510(k) Number (if known): K123335

Device Name: Fetal Monitor, model: SRF618B5

Indications for Use:

SRF618B5 Fetal Monitor detects and displays single or twin (optional) Fetal Heart Rate (FHR), Fetal Movement (FM) and Uterine Activity (UA) in a real time on the color LCD viewer, and also provides the fetal heart beat sound with internal speaker. Ten hours of tracing may be stored and later retrieved for printing. It is intended for antepartum use by trained healthcare personnel. It is not intended for home use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123335

510(k) Number_____

Diagnostic Ultrasound Indications for Use Form

System: Fetal Monitor, model: SRF618B5 **Transducer: 2MHz PW Probe**

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body for antepartum use as follows:

Clinical Application	Mode of Operation						
	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic							
Fetal / Obstetrics			N				
Abdominal							
Intra-operative (Specify)							
Intra-operative (Neurological)							
Laparoscopic							
Pediatric							
Small Organ (Specify)							
Neonatal Cephalic							
Adult Cephalic							
Transrectal							
Transvaginal							
Transurethral							
Musculo-skeletal (Conventional)							
Musculo-skeletal (Superficial)							
Intravascular							
Cardiac							
Intravascular							
Peripheral vascular							
Other (Urology)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

Additional Comment: The above probe is a 2 MHz PW transducer for the fetal heart rate (FHR) detection. There are two FHR transducers in this device. These two transducers are the same. Use one for single fetus, use two for twins.

Herbert P. Lerner -S
2013.03.21 15:41:47 -04'00'